

Although he has left us too soon, the impact of Judge Alan Rosenfield's life will not soon be forgotten. Our communities are safer and our lives richer because of the life and service of Judge Rosenfield. We will continue to keep the Rosenfield family in our prayers, and we are thankful that our community was blessed enough to have Alan as a leader in the justice system.

TRIBUTE TO JEAN MCCOWN ON  
HER RETIREMENT

**HON. ANNA G. ESHOO**

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

*Wednesday, June 15, 2022*

Ms. ESHOO. Madam Speaker, I rise today to honor Jean McCown, her career in public service, and as Associate Vice President of Government Affairs at Stanford University. Jean is a graduate of the University of Michigan and Boalt Hall Law School. Before joining Stanford in 2004, she was a partner at the law firm of Ritchey Fisher Whitman & Klein, where she focused on land use, environmental and real estate matters.

Jean was a member of the Palo Alto City Council from 1990 to 1998 and served as mayor in 1993. She previously served on the Palo Alto Planning Commission and on regional transportation committees including the CalTrain Joint Powers Board and the Metropolitan Transportation Commission.

Jean McCown served on the board of the Greenbelt Alliance for many years and is now a board member of the Palo Alto Community Foundation and Alta, formerly the Palo Alto Housing Corporation.

The honors she has earned include the John W. Gardner Leadership Award in 1994 from American Leadership Forum Silicon Valley, and the Palo Alto Chamber of Commerce Athena Award in 2004.

As Associate Vice President within the Office of Government Affairs at Stanford, Jean McCown focused on the University's government and community affairs efforts and initiatives at the city, county and state level. She maintained relationships with community-based organizations, government officials, local businesses and citizens to support effective communication and dialogue within the Stanford community and between Stanford and its neighbors. While at Stanford she provided strategic leadership for the Searsville Watershed Restoration project and provided strategic guidance for the Middle Plaza Housing Project in Menlo Park. She helped build supportive relationships with the Palo Alto Unified School District and secured the fire services contract between Stanford and the Palo Alto Fire Department. Jean led multiple General Use Permit negotiations with Santa Clara County, provided strategic guidance for the Hospitals Renewal projects for the Stanford adult and children's hospitals, and helped spearhead the Palo Alto Mayfield agreement creating new public playing fields and housing for the City.

Madam Speaker, I ask the entire House of Representatives to join me in honoring Jean McCown for her extraordinary work and in wishing her every blessing in her well-deserved retirement.

HOMETOWN HERO—JEWISH  
COMMUNITY CENTER OF DALLAS

**HON. BETH VAN DUYNE**

OF TEXAS

IN THE HOUSE OF REPRESENTATIVES

*Wednesday, June 15, 2022*

Ms. VAN DUYNE. Madam Speaker, I rise today to recognize the Jewish Community Center of Dallas, which has gone above and beyond to better our community.

The JCC's mission is to bring the North Texas Jewish community together with their incredible facilities and programs, however they have done so much more than that.

Each year, the JCC provides over 18,000 hot meals to North Texan seniors, regardless of race or religion. As the pandemic loomed, the JCC's resolve was unwavering. They continued their senior meal service with an innovative drive-thru feature to keep seniors safe and well fed.

The Jewish Community Center's compassion and service to its community should serve as an inspiration to all North Texans. I thank the JCC for going above and beyond to ensure North Texas is a brighter place to live every single day.

PASSAGE OF H.R. 7667, THE FOOD  
AND DRUG AMENDMENTS OF 2022

**HON. PRAMILA JAYAPAL**

OF WASHINGTON

IN THE HOUSE OF REPRESENTATIVES

*Wednesday, June 15, 2022*

Ms. JAYAPAL. Madam Speaker, I rise today on the passage of H.R. 7667 the "Food and Drug Amendments of 2022." Though I am grateful for many of the provisions in this bipartisan legislation, I have strong concerns that this bill does not go far enough to protect the American people—both patients and their doctors. This reauthorization, only occurring every five years, is one of our greatest opportunities to hold the pharmaceutical industry accountable and to the highest standards possible to ensure access and protection for patients across the country.

Typically, this routine reauthorization of user fees is coupled with incentives directed toward the pharmaceutical and medical device industry. With each reauthorization to date, we have seen the increased adoption of expedited review pathways leaving patients and their doctors more uncertain that FDA approved treatments are truly effective or safe. Often, these new pathways that hasten FDA's regulatory review are coupled with financial incentives including exclusivity periods that prolong high monopoly prices such that the American public is paying more for less. Last year's controversial approval of the Alzheimer's disease drug, aducanumab (Aduhelm) laid bare this reality when the FDA approved this drug under the accelerated approval pathway despite harms including brain bleeding and swelling as well as uncertain clinical benefit. This shifted the focus of this year's user fee reauthorization efforts away from shortening FDA review times for new health technologies to reforms to reinstate public trust into FDA's approval process.

FDA's accelerated approval pathway can be an important way for promising drugs to reach patients. But pharmaceutical corporations

have largely failed to uphold their end of the bargain of completing critical studies to confirm that these drugs are truly beneficial. Instead, accelerated approval is being used by Big Pharma to drive further profits at the expense of patient safety and Medicare spending. Although H.R. 7667 would allow for greater FDA oversight of the accelerated approval pathway, this bill should have included much stronger reforms for accelerated-approval drugs.

This bill should have made sure that FDA publicly engages with their advisory committees instead of industry sponsors behind closed doors. Recent studies have found that FDA has convened these independent experts less frequently—between 2010 and 2021, FDA went from hearing these groups for 55 percent of approved drugs to just 6 percent. Transparency is paramount to ensuring trust in our government institutions. We should codify that meetings are made public and nothing should obscure a patient's ability to see how and why a therapeutic approval was granted.

Moreover, the bill should ensure that lower standards of evidence cannot be accepted to approve a drug. Clarification is needed to ensure that Real World Evidence (RWE) is appropriately used to augment the post-approval studies that prove therapies approved are truly effective and research has shown that RWE has demonstrated promise for complementing clinical trials but not replacing them. When it comes to the safety of our constituents, we must ensure that speedy access does not eclipse safety.

A recent study published in JAMA Health Forum explored how much Medicare and Medicaid spend on drugs granted accelerated approval by the FDA both before and after the drug's clinical benefit is confirmed. The study found that for the 38 drugs granted accelerated approval by the FDA between 2012 and 2017:

CMS spent almost \$70 billion through 2020 on these drugs;

just over \$50 billion (75 percent) was spent after the accelerated approval drugs were converted to standard approval following completion of their required confirmatory trials; but

almost 60 percent (\$40 billion) of this spending was for drugs with confirmatory trials evaluating surrogate endpoints instead of assessing meaningful clinical endpoints demonstrating the effect of these drugs on how patients feel, function, or survive.

In addition, this bill should squarely place patient safety at its core and mandate the automatic withdrawal of drugs, preliminarily approved under accelerated approval, that fail to prove efficacy. Not explicitly mandating that approval should expire one year after any target date of study completion, and in no case later than five years after the product is approved unless certain criteria relative to post approval studies are achieved, is a significant concession to the pharmaceutical industry that puts patients and payers at risk of prolonged medical and financial harms. There should be no barriers to removing a drug that at best is ineffective and at worst dangerous.

Another troubling inclusion in the approved measure are additional provisions that would empower a sponsor company to request a meeting with the FDA Commissioner, a public comment period followed by responses by the agency, and a convening of the advisory committee to review the agency's request for withdrawal, wasting precious time. Rather, the